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## REMARKS

Reconsideration of this application in view of the following remarks is respectfully requested.

### I. Amendments to the claims

Claims 1, 7, 12, 14 and 15 have been amended to include glycerin. Claims 19 and 20 has been canceled and new claims 21-26 have been added. Support for including glycerin can be found in Example 2, page 13, lines 21-22, and page 15, lines 4-6. Support for the amendment of claim 12 can be found on page 19, lines 6 and 7. Support for new claims 21-26 can be found in Example 2 and on page 15, lines 13-15. Claims 1-18 and 21-26 are now pending in this application. No new matter has been added as a result of this amendment.

### II. Claim Objections under 37 C.F.R. §1.75

Claim 20 was objected to for allegedly being a duplicate of claim 14. Applicant has canceled claim 20. Accordingly, Applicant respectfully request that the objection to claim 20 is now moot.

### III. Claim Rejections under 35 U.S.C. §101

Claims 1-6 were provisionally rejected under 35 U.S.C. §101 as claiming the same invention as claims 5-10 of co-pending application No. 11/238,449. The Examiner asserted that present claims 1-6 are the same as claims 5-10 of co-pending application No. 11/238,449 (the '449 application). Applicant respectfully submits that claims 1-6 of the present application are not the same as claims 5-10 of co-pending '449 application.

Present claims 1-6, as amended, are directed to compositions for treating a dermatological inflammatory response. In contrast, claims 5-10 of co-pending application no. 11/238,449 are directed to compositions for treatment of ***oral mucosal*** inflammatory response which is not the same as the presently claimed compositions. Accordingly, Applicant respectfully request that the rejection of present claims 1-6 under 35 U.S.C. §101 based on claims 5-10 of the '449 application be withdrawn.

### IV. Double Patenting Rejections

Claims 1-15 and 19-20 were provisionally rejected under nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9-13, and 16-19 of U.S. Pat. No. 5,174,990, and over claims 1, 8-12, and 15-17 of U.S. Pat. No. 5,310,546. Claims 12 and 15-19 were also provisionally rejected under nonstatutory obviousness-type double patenting as being unpatentable over claims 11-16 of co-pending application No. 11/238,449.

Present claims 1-18 are directed to compositions for treating a ***dermatological*** inflammatory response, methods for treating a ***dermatological*** inflammatory response, and methods for preparing a composition for treating a ***dermatological*** inflammatory response. In contrast, claims 1, 9-13, and 16-19 of U.S. Pat. No. 5,174,990 (the "'990 patent"), and claims 1, 8-12, and 15-17 of U.S. Pat. No. 5,310,546 (the "'546 patent") are directed to ***mouth rinse*** compositions with different components and ranges of components. Claims 11-16 of co-pending application No. 11/238,449 are directed to treating inflammatory response but not to a dermatological inflammatory response using the specific composition recited therein.

Notably, the present claims are directed for treating a dermatological inflammatory response, that is, treating a dermatological area which includes skin, scalp and nails but not oral mucosa found in the mouth. The dermatological surface of the present claims refers to the skin, ***not*** the mouth as required under the recited claims of the '990 and '546 patents. The present claims are directed to treating the dermatological inflammation as is taught throughout the present specification, particularly on page 16, lines 12-20 and Examples 1 and 2.

Accordingly, present claims 1-18 cannot be rejected based on the '990 and '546 patents and the '449 application. Withdrawal of the double patenting rejections of the present claims is in order and is respectfully requested.

## V. Claim Rejections under 35 U.S.C. §102(b)

The Examiner rejected claims 1-11, 14, 15, 19 and 20 as allegedly anticipated by U.S. Pat. No. 5,104,644 (the "'644 patent"). Specifically, the Examiner asserted that the subject matter of instant claims 1-11, 14-15, and 19-20 is contained in the '644 patent because the '644 patent teaches a mouth rinse preparation that contains about 0.5 to about 3 % hydrogen peroxide, final pH of about 3.5 to about 4.0 or about 3.5-5.5 or 6-7, disodium EDTA, glycerin, zinc chloride, sodium lauryl sulfate, citric acid, and sodium citrate. In addition, the Examiner asserted that the mouth rinse preparation of the '644 patent is useful to check inflammatory processes responsible for gingivitis and heal hemorrhagic tissue.

The Examiner also rejected claims 1-6 as allegedly anticipated by U.S. Pat. No. 6,086,856 (the "'856 patent"). Particularly, the Examiner asserted that the subject matter of instant claims 1-6 are taught by the '856 patent because the '856 patent teaches oral hygiene formulations comprising hydrogen peroxide, zinc chloride, sodium citrate, citric acid, and sodium lauryl sulfate.

Further, the Examiner rejected claims 1-5, 7-11, 14-15 and 19-20 as allegedly anticipated by U.S. Pat. No. 5,174,990 (the "'990 patent") or U.S. Pat. No. 5,310,546 (the "'546 patent"). Particularly, the Examiner asserted that the subject matter of instant claims 1-5, 7-11, 14-15 and 19-

20 are described in the '990 patent or the '546 patent because the '990 patent or the '546 patent teaches a mouth rinse preparation for reducing inflammation containing hydrogen peroxide, zinc chloride, sodium citrate, sodium lauryl sulfate, citric acid, glycerin, disodium EDTA and a pH from about 3.5 to about 4.5.

Applicants respectfully submit that the instant claims are not anticipated by any one of the cited references because each of the cited references do not teach the compositions or the methods of the present claims directed to treating a dermatological inflammatory response.

In order for a reference to anticipate the claims of an invention, that reference must teach each and every element set forth in the claims, either expressly or inherently. M.P.E.P. § 2131; Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987) and EMI Group N. Am., Inc. v. Cypress Semiconductor Corp., 268 F.3d 1342, 1350 (Fed. Cir. 2001). According to the Federal Circuit, an anticipatory reference must disclose "[t]he identical invention in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989). Further, "[a]n anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed." ATD Corp. v. Lydall, Inc., 159 F.3d 534, 545 (Fed. Cir. 1998). Further, even if a reference discloses a range that touches, overlaps or is within the claimed range and fails to teach an example within the claimed range, the reference does not anticipate the claimed range. M.P.E.P § 2131.03(II). Thus, if at least one element or limitation of the claims is missing from a reference, then that reference cannot support an anticipation rejection under 35 U.S.C. §102.

The present claims are directed to compositions and methods for treating a ***dermatological*** inflammatory response. The compositions of claims 1-11 and 14 comprise components that render the compositions useful for treating a ***dermatological*** inflammatory response. Similarly, the method claims 15-18 are directed to methods for treating a ***dermatological*** inflammatory response using compositions that comprise components that render the compositions useful for treating a dermatological inflammatory response. Compositions or methods for treating a dermatological inflammatory response means treating a dermatological area. A dermatological area refers to the skin (see attached page copy of Webster's Third International Dictionary, copyright 1993). Skin refers to the external limiting layer of an animal body consisting of the epidermis and dermis as well as hair, hair follicles, glands and keratinized outer surface (see attached page copy of Webster's Third International Dictionary, copyright 1993). A dermatological surface does not include the oral or buccal cavity, such as the mouth.

Therefore, for any of the cited references to anticipate the present claims, the reference must describe compositions and methods useful for treating a dermatological inflammatory

response. There must be a specific and clear teaching in a cited reference that a composition and a method as described in the present claims is used for treating a dermatological inflammatory response, just as the present claims require. For the cited references to anticipate the present claims, the references must teach compositions having the exact ingredients and concentration ranges of the ingredients as the ingredients and concentration ranges of the ingredients recited in the present claims. Moreover, the references must teach of a composition or method for treating a dermatological inflammatory response, as recited in the present claims. Applicant submits that the present claims are not anticipated by any of the cited references because each of the cited references fails to teach the concentration ranges as well as the composition and method according to the present claims for treating a dermatological inflammatory response.

Each of the cited references is directed to mouth rinse compositions and to methods of preparing these oral compositions. The focus of each of the cited references, that is, the problem solved, is compositions for oral therapy. Nothing in the cited references teaches a composition or a method for treating a skin condition, specifically, a dermatological inflammatory response. The oral cavity of the cited references is not a dermatological area like the skin. The present claims are directed for treating a dermatological inflammatory response, that is, treating a dermatological surface. The dermatological surface of the present claims refers to the skin which is the external limiting layer of an animal body consisting of the epidermis and dermis as well as hair, hair follicles, glands and keratinized outer surface. A dermatological area, therefore, does not include the oral or buccal cavity of the cited references. Indeed, the cited references are directed to treating the oral cavity that comprises the mouth, not the skin. The present claims are directed to treating the skin. For example, page 16, lines 12-20 and Examples 1 and 2 of the present specification teaching that the compositions of the claims are applied topically to the skin. For at least this reason, each of the cited references cannot anticipate the present claims.

**The '644 Patent**

The cited reference '644 patent teaches a ***mouth rinse*** preparation that contains hydrogen peroxide, zinc chloride, sodium lauryl sulfate, citric acid, glycerin and sodium citrate in amounts as recited in Examples 1-3 as well as in col. 7, line 3 to col. 8, line 68. See Abstract. The specific problem solved in the '644 patent is the problem of obtaining a mouth rinse composition for killing bacteria responsible for dental diseases as well as healing oral edematous tissue and hemorrhagic tissue and checking inflammation to prevent oral gingivitis (see col. 1, lines 9-15, col. 3, line 67 to col. 4, line 6, and col. 6, lines 6-56). The '644 patent is directed to compositions having a specific concentration range of components for maintaining healthy oral cavity (see col. 1, lines 16-17), not

to composition for treating a dermatological inflammatory response. In addition, the '644 Examples are all directed specifically to mouth rinse compositions, see Example 1, for instance. The ranges of the ingredients of the '644 compositions are not the same as the ranges of the ingredients as recited in the present claims. Moreover, nowhere in the '644 patent is there any teaching or suggestion of any composition or method useful for treating a dermatological inflammatory response. Thus, the '644 patent fails to anticipate the present claims.

The Examiner cited the Abstract, col. 1, lines 9-25, col. 3, line 67 to col. 4, line 6, col. 6, lines 59-65, col. 9, lines 5-13, col. 9, lines 36-45, and Example 1 of the '644 patent to support the anticipatory rejections of the present claims directed to compositions and methods for treating a dermatological inflammatory response. But as extensively pointed above, the cited sections of the '644 patent focus on mouth rinse composition for killing bacteria responsible for dental diseases and checking inflammation to prevent oral gingivitis. Thus, the '644 patent cannot operate as an anticipatory reference to the present claims. Withdrawal of the section 102(b) rejection of claims 1-11, 14, 15, 19 and 20 based on the '644 patent is in order and is respectfully requested.

**The '856 Patent**

Similarly, the '856 patent also fails to describe a composition useful for treating a dermatological inflammatory response. The '856 patent describes ***oral hygiene*** formulations comprising a foaming surfactant (see the Abstract). The formulation of the '856 patent is useful for treating and preventing tooth decay, gingivitis and periodontal disease (see col. 3, lines 6-8), not for treating a dermatological inflammatory response as recited in the present claims. In fact, the '856 patent specifically states that the formulations are foamable mouthcare formulations, such as mouthwashes, rinses, and dentrifices (see col. 3, lines 32-34). The ranges of the ingredients of the '856 compositions are not the same as the ranges of the ingredients as recited in the present claims. In addition, all the specific examples of the '856 patent are focused on mouth rinse or mouthwash formulations (Example 1, 5-7), anti-plaque dental rinse formulations (Example 2-4), and non-ingestible expectoratable formulations (Example 8). The '856 patent does not teach a composition for treating a dermatological inflammatory response, as the present claims. In an attempt to support the anticipatory rejections of the claims, the Examiner cited the Abstract and col. 11, lines 33-45 (Example 5) of the '856 patent. But the cited sections do not teach or suggest any formulation for treating a dermatological inflammatory response as recited in the present claims. Therefore, the '856 patent also fails to anticipate the present claims. Withdrawal of the section 102(b) rejection of claims 1-6 based on the '856 patent is in order and is respectfully requested.

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**The '990 and '546 Patents**

Like the '644 and '856 patents, the '990 and '546 patents also fall short of being anticipatory references because the '990 and '546 patents do not teach a composition or a method comprising a composition for treating a dermatological inflammatory response. The '546 patent is a continuation of the '990 patent, and so their disclosures are the same. The ranges of the ingredients of the '990 and '546 compositions are not the same as the ranges of the ingredients as recited in the present claims. Both patents are directed to ***mouth rinse*** preparations for oral therapy and prevention of dental disease (see Abstract, col. 1, lines 12-14, and col. 2, lines 49-51). Indeed, the compositions of the '990 and '546 patents possess effective antibacterial properties against a spectrum of microorganisms representing odontopathogens associated with different oral diseases (see Example 4). As such, both '990 and '546 patents fail to teach a composition for treating a dermatological inflammatory response, as the present claims. Even so, the Examiner cited the Abstract, claims 1, 9-10 and 12 and 13, col. 3, lines 15-17, col. 3, lines 35-40, col. 3, lines 47-48, col. 3, lines 53-59, col. 4, lines 20-21, col. 4, lines 24-26, and Examples 2-4 to support anticipation of the claims. But, as discussed above, the specification of the '990 and '546 patents, including the cited sections, do not teach any composition or method for treating a dermatological inflammatory response as recited in the present claims. Thus, the '990 and '546 patents cannot anticipate the present claims. Withdrawal of the section 102(b) rejections of claims 1-5, 7-11, 14, 15, 19 and 20 based on the '990 patent and '546 patent are in order and are respectfully requested.

As discussed above, the each of the cited references fail to anticipate present claims 1-11, and 14-15. Each of the cited references do not teach a composition comprising the same ingredients as recited in present independent claims 1, 7 and 14 as well as the same recited ranges. In addition, the cited references fail to teach compositions and methods treating a dermatological inflammatory response. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejections under 35 U.S.C. §102(b).

**VI. Claim Rejections under 35 U.S.C. § 103(a)**

Claims 15-19 were rejected under 35 U.S.C. 103(a) as being unpatentable over the '644 patent in view of the '856 patent. The Examiner asserted that the limitations of claims 15-19 are taught by '644 in view of '856 because the '644 patent teaches a method of applying once a day and the '856 patent teaches a method for delivering non-ingestible expectoratable formulations to the oral cavity. On this basis, the Examiner concludes that the present invention would be obvious to one skilled in the art since both the '644 patent and the '856 patent are directed to mouthwash using

$H_2O_2$.

The Examiner also rejected claims 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over the '990 patent in view of the '546 patent. The Examiner asserted that each of the '990 patent or the '546 patent teaches zinc chloride solutions prepared by adding zinc chloride to deionized water and allowing heat dissipation. Thus, the Examiner concluded claims 12 and 13 are obvious to one of ordinary skill in the art in determining how long to wait for heat to dissipate or to vary mixing times.

Applicants respectfully submit that the Examiner has failed to establish a case of obviousness. Obviousness rejections cannot be sustained by mere conclusory statements; instead, there must be some explicit and articulated reasoning with rational underpinnings to support the legal conclusion of obviousness. KSR International Co. v Teleflex Inc., No. 04-1350 (U.S. Supreme Court, April 30, 2007, at page 14). Moreover, the test of obviousness under 35 U.S.C. §103 hinges on four factual findings which the Patent Office must follow in determining obviousness. Graham v John Deere Co., 383 U.S. 1, 17. The inquiry includes determining the scope and content of the prior art, ascertaining the differences between the prior art and the claims at issue; resolving the level of ordinary skill in the pertinent art, and evaluating any evidence of secondary considerations as objective evidence of nonobviousness. Nat'l Steel Car, Ltd., v. Can. Pac. Ry., Ltd., 357 F.3d 1319, 1334 (Fed. Cir. 2004). Moreover, where there is a range disclosed in the prior art and the claimed range is encompassed within the range, the patentee must show that the claimed recited range achieves some unexpected results. *Iron Grip Barbell Co. v. USA Sports Inc.*, 392 F.3d 1317 (Fed. Cir. 2004) (citing to *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990)).

Present claims 12 and 13 directed to methods for preparing a composition for treating a dermatological inflammatory response. Claims 15-18 are directed to methods for treating a dermatological inflammatory response with a specific composition. For present claims 15-18 to be obvious over the '644 patent in view of the '856 patent, the '644 patent in combination with the '856 patent must teach or suggest to one skilled in the art a method using a composition as recited in the present claims for treating a dermatological inflammatory response. In addition, for present claims 12 and 13 to be obvious over the '990 patent or the '546 patent, the '990 patent or the '546 patent must teach or suggest to one skilled in the art a method for preparing a composition for treating a dermatological inflammatory response. Applicant submits that when the *Graham* factors are considered in view of the cited references, present claims 12, 13 and 15-18 are not obvious because one skilled in the art could not arrive at the invention of the present claims by relying on the cited references.

Applicant respectfully submits that the Examiner has not established a case of obviousness

on the basis of the combination of the '644 patent and the '856 patent, or on the basis of the '990 patent or the '546 patent, principally because the Examiner has not provided an explicit and articulated reasoning with rational underpinning to support the legal conclusion of obviousness as required by KSR International Co. The Examiner has merely cited certain sections in the references and provided conclusory statements to assert the obviousness rejections.

Contrary to the Examiner's assertion, present claims 15-18 are not obvious over the '644 patent in view of the '856 patent because after considering the '644 and the '856 patents as a whole in view of the *Graham* factors, it would not be obvious to one of ordinary skilled in the art to combine the teachings of the '644 and the '856 patents concerning mouth rinses and derive a reasonable expectation of success of arriving at the methods for treating a dermatological inflammatory response as recited in present claims 15-18. Similarly, claims 12 and 13 are not obvious over the '990 patent or the '546 patent because it would not be obvious to one of ordinary skilled in the art to rely on teachings of the '990 or the '546 patent concerning dental treatments to arrive at the methods for preparing a composition for treating a dermatological inflammatory response as recited in present claims 12 and 13. Applicant now turns to the analysis of the *Graham* factors to show that present claims 12 , 13 and 15-18 are not obvious in view of the cited references.

**Scope and Content of the Cited References**

The '644 patent teaches a mouth rinse preparation that contains hydrogen peroxide, zinc chloride, sodium lauryl sulfate, citric acid, glycerin and sodium citrate in amounts as recited in Examples 1-3 as well as in col. 7, line 3 to col. 8, line 68. The '644 composition is useful as a mouth rinse preparation (see Abstract). The specific problem solved in the '644 patent is the problem of obtaining a mouth rinse composition for killing bacteria responsible for dental diseases as well as healing edematous tissue and hemorrhagic tissue and checking inflammation to prevent gingivitis (see col. 1, lines 9-15, col. 3, line 67 to col. 4, line 6, and col. 6, lines 6-56). The '644 patent is directed to compositions for maintaining healthy oral cavity (see col. 1, lines 16-17), not to composition for treating a dermatological inflammatory response. In addition, the '644 Examples are all directed specifically to ***mouth rinse*** compositions, see Example 1, for instance. Nowhere in the '644 patent is there any teaching or suggestion that the composition can be use in a method for treating a dermatological inflammatory response.

The '856 patent describes oral hygiene formulations comprising a foaming surfactant (see the Abstract). The formulation of the '856 patent is useful for treating and preventing tooth decay, gingivitis and periodontal disease (see col. 3, lines 6-8), not for treating a dermatological inflammatory response, as the present claims. In fact, the '856 patent specifically states that the

formulations are foamable mouth care formulations, such as mouthwashes, rinses, and dentrifices (see col. 3, lines 32-34). In addition, all the specific examples of the '856 patent are focused on mouth rinse or mouthwash formulations (Example 1, 5-7), anti-plaque dental rinse formulations (Example 2-4), and non-ingestible expectoratable formulations (Example 8). The '856 patent does not teach a composition for use in a method treating a dermatological inflammatory response, as recited in present claims 15-19. The Examiner cited the Example 8, but Example 8 describes non-ingestible expectoratable foaming formulations that can be used up to four times daily in the mouth, not a methods comprising a composition for treating a dermatological inflammatory response, as recited in present claims 15-19.

The '990 and '546 patents are directed to mouth rinse preparations for oral therapy and prevention of dental disease (see Abstract, col. 1, lines 12-14, and col. 2, lines 49-51). Indeed, the compositions of the '990 and '546 patents possess effective antibacterial properties against a spectrum of microorganisms representing odontopathogens associated with different oral diseases (see Example 4). The Examiner cited Example 1 of the '990 and '546 patents in an attempt to show a teaching or a suggestion for a method for preparing a composition for treating a dermatological inflammatory response, similar to the method of present claims 12 and 13. But Example 1 like the remainder of the '990 or '546 patents focus entirely on mouth rinse preparations for oral therapy and dental disease, and a method for preparing such mouth rinses.

**The Differences Between the Cited References and the Claims**

The '644 and '856 patents are directed to compositions useful for treating oral conditions. Unlike the '644 and '856 patents, present claims 15-18 are directed to a method comprising a composition for treating a dermatological inflammatory response. There is no teaching or suggestion in either the '644 patent or the '856 patent, or in their combination, of a method comprising a composition for treating a dermatological inflammatory response.

Similarly, the '990 and the '546 patents are directed to a composition and a method for preparing a composition useful for treating dental diseases. Present claims 12 and 13 are directed to methods for preparing a composition for treating a dermatological inflammatory response. Nowhere in the '990 patent or the '546 patent is there a teaching or suggestion of a method for preparing a composition for treating a dermatological inflammatory response.

**Level of Ordinary Skill in the Pertinent Art**

With respect the '644 patent and the '856 patent, both the '644 patent and the '856 patent are of at least the level of ordinary skill in the pertinent art, yet the invention of present claims 15-18

did not occur to any one of them. Specifically, neither the '644 patent or the '856 patent provides any teaching or suggestion that their compositions can be used in a method for treating dermatological inflammatory response. Indeed, both the '644 patent and the '856 patent fail to even suggest any composition that can be used for treating dermatological inflammatory response.

Similarly, the '990 and the '546 patents are of at least the level of ordinary skill in the pertinent art, but failed to teach or suggest a composition that can be used for treating dermatological inflammatory response, and, even more so, a method for preparing a composition for treating dermatological inflammatory response, like recited in present claims 12 and 13.

Thus, after considering the *Graham* factors, one of ordinary skill in the pertinent art would not see it as an obvious step to combine the teachings of the '644 patent and the '856 patent in order to arrive at present claims 15-18. It is also not obvious to one of ordinary skill in the art to derive from the '644 patent and the '856 patent methods for treating a dermatological inflammatory response comprising a composition as recited in present claim 15 because the patents teach or suggest nothing in the nature for treating a dermatological inflammatory response. The teachings of '644 patent and the '856 patent relating to dental therapy provide no motivation to make such a combination. But the Examiner still asserted that one of ordinary skill in the art would be motivated to combine the ranges of Example 1 in the '644 patent with Example 5 of the '856 patent to know how often to use the medicament. One skilled in the art would indeed combine the '644 patent with the '856 patent if the problem was how to administer a composition in a method for treating oral diseases to which the '644 and '856 patents are directed to. But a skilled person would not look at the '644 patent in combination with the '856 patent to solve the problem of treating a dermatological inflammatory response comprising a composition as recited in present claim 15.

The cited references are directed to compositions useful as mouth rinse, and to methods of preparing the oral compositions. The focus of each of the cited references, that is, the problem solved, is compositions for oral therapy. Nothing in the cited references teaches a composition or a method for treating a skin condition, specifically, a dermatological inflammatory response. The oral cavity of the cited references is not a dermatological area like the skin. The present claims are directed for treating a dermatological inflammatory response, that is, treating a dermatological area. The dermatological area of the present claims refers to the skin which is the external limiting layer of an animal body consisting of the epidermis and dermis as well as hair, hair follicles, glands and keratinized outer surface. A dermatological area, therefore, does not include the oral or buccal cavity of the cited references. Indeed, the cited references are directed to treating the oral cavity that comprises the mouth, not the skin. The present claims are directed to treating the skin. For example, page 16, lines 12-20 of the present specification teaching that the compositions of the

claims are applied topically to the skin, not the mouth. In addition, Examples 1 and 2 further teach compositions useful for treating dermal inflammation. Thus, the subject matter of the present claims would not be obvious to a skilled artisan from the cited references.

Similarly, a skilled person would not look at the '990 patent or even the '546 patent when the problem is directed to obtaining methods for preparing a composition for treating a dermatological inflammatory response comprising the specific steps as recited in present claim 12. In particular, it is not obvious to one of ordinary skill in the art from the description in the '990 patent or the '546 patent to include an incubating step like present claim 12 for 5-10 minutes and another incubating step of at least 4 hours, or to even include additional mixing steps lasting from 30 to 60 minutes. Example 1 in the '990 and '546 patents were cited by the Examiner to support the obviousness rejection, but Example 1 does not teach or suggest the incubating and mixing times of present claims 12 and 13. A skilled artisan, even one of skill at the Ph.D. level, would not look at Example 1 of the '990 and '546 patents for inventing present claims 12 and 13 because the '990 and '546 patents are not even directed to compositions for treating a dermatological inflammatory response, much less to methods for preparing such compositions for treating a dermatological inflammatory response. For the skilled artisan to know the times for incubating and mixing, the artisan would have to perform experimentation, just as Applicant did in inventing present claim 12 and 13.

Deriving methods for treating a dermatological inflammatory response comprising a composition or methods for preparing a composition useful for treating a dermatological inflammatory response from unrelated dental teachings would not be possible. One of ordinary skill in the art would know better than to merely combine different elements from unrelated fields to successfully arrive at a composition that can be used in methods for treating a dermatological inflammatory response. The '644, '856, '990 and '546 patents are in the field of formulations for oral therapy, not in the dermatological field. As such, the cited references provide no guidance to one of ordinary skill to derive methods for treating a dermatological inflammatory response comprising a composition or methods for preparing a compositions useful for treating a dermatological inflammatory response. It is not obvious to use the oral formulations of the cited references to arrive at methods for treating a dermatological inflammatory response comprising a composition, or even to arrive at methods for preparing a compositions useful for treating a dermatological inflammatory response. Nothing, absolutely nothing in the cited references provide a teaching or even a sparkle of a suggestion to a person of ordinary skill or creativity to extract from the cited references the invention of present claims 12 and 13 and 15-18. Accordingly, claims 12 and 13 and 15-19 are unexpected results that could not have been predicted from the cited references.

Thus, Applicant submits that claims 12 and 13 and 15-19 are not obvious over the cited references. Accordingly, Applicant respectfully submit that withdrawal of the rejection under 35 U.S.C. 103(a) based on the aforementioned references is in order.

## VII. Conclusion

In light of the above discussion, the Applicants submit that the claims are in allowable condition. A Notice to this effect is respectfully requested.

Reconsideration of this application is respectfully requested and a favorable determination is earnestly solicited. The Examiner is invited to contact the undersigned representative if the Examiner believes this would be helpful in expediting the allowance of this application.

Dated: June 27, 2007

Respectfully submitted,

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name from an Indian chief) (the mills ~ their power from the falls) (he ~s much of his income from investments) b : to obtain or gain through heredity or by transmission from environment or circumstance (he *derived* his enthusiasm for the theater from his father) (*deriving* certain dignity from battles fought and won —Richard Llewellyn) (the word *girl* is *derived* from Middle English *girle*) c : to acquire, get, or draw (as something pleasant or beneficial) (the satisfaction *derived* from a sense of sharing in creative activities —John Dewey) (the mutual benefits that nations can ~ from trading which flows in both directions —*Lamp*) d : amass (a movie *derived* from a novel) e : to obtain (a substance) actually or theoretically from a parent substance (as by substitution or hydrolysis) — compare DERIVATIVE 4 **2** *archaic* : to divert (as water) from its source or normal course **3** : to gather or arrive at (as a conclusion) by reasoning and observation **a** : to obtain inductively (ideas *derived* from nature) : INFER **b** : PROVOKE (*propositions derived* from reform) **4** *archaic* : to pass along : TRANSMIT **5** *archaic* : to cause to exist (inconvenience that will be *derived* to them from stopping all imports —Thomas Jefferson) **6** : to trace the origin, descent, or derivation of (we can ~ English *chauffeur* (from French) (~ *toaster* from *toast*) (an early theory *derived* speech from involuntary cries) **7** : to be descended or formed from (all were probably *derived* from the same ancestral stock —H.L.F.A. Menckiu) : be a derivative of (the plural is normally *derived* from the singular) ~ vi **1** *archaic* : DESCEND **2** : to have or take origin : ORIGINATE : STEM, EMANATE : come as a derivative — usu. used with *from* (all knowledge ~s from sensations —J.H.Randall) (half of his income ~s from wheat) (the social stratum from which he *derived* —Carl Van Doren) (stories *deriving* from his experiences in Africa) syn see STRING

**derived** *adj* **1** : formed or developed out of something else : DERIVATIVE : reflected or secondary in character : not original or primary (the belief that individuals are alone real, that classes and organizations are secondary and *derived* —John Dewey) **2** : brought from elsewhere : not native (*derived* fossils)

**derived curve** *n* : the graph of the derivative of a function of one variable whose graph is the given curve — called also *first derived curve*

**derived function** *n, math* : the derivative of a given function — called also *first derived function*

**derk** \'dərk\ *chiefly Scot var of* DARK

**derm** \'dərm, ,dəm-,sām\ *n* -s [NL *derma & dermis*] **1** : DERMIS **2** : SKIN 2a **3** : CUTICLE 1a

**derm-** *or* **dermo-** *or* **dermato-** *comb form* [NL, fr. Gk *derm-, dermo-, dermat-*, fr. *derein* to flay — more at TEAR] **1** : skin (*dermalgia*) (*dermatherma*) (*dermoskeleton*) **2** : dermal and (*dermatomeral*)

**-derm** \,dərm, ,dəm-,sōm\ *n comb form* -s [prob. fr. F *-derme*, fr. Gk *derma*] : skin : covering : integument (*blastoderm*)

**der·ma** \'dərmə, ,dəm-,sōmə\ *n* -s [NL, fr. Gk *derma* skin — more at TEAR] **1** : DERMIS **2** : the inner part of the skin of which leather is made, the fat cells and tissues determining the character of leather that can be produced

**der·ma** \"\ *n pl but often sing in constr* [Yiddish *derme*, pl. of *durim* intestine, gut, fr. MHG, fr. OHG *thurm, doram*; akin to OE *thearm* gut, OFris *therin*, ON *tharmr* gut, Gk *termōn* hole — more at TERM] : beef casings — see KOSHER

**-der·ma** \'dərmə, -,dəmə, -,dāmə\ *n comb form, pl* **-derm·as** \-məz\ *or* **-derm·a·ta** \-mədə, -mətə\ [NL, fr. Gk *derma, dermat-*] **1** : skin : covering : integument (*sarcoderma*) **2** : skin or skin ailment of a (specified) type (*scleroderma*) **3** : one having a (specified) type of skin — in generic names (*Heloderma*)

**der·ma·cen·tor** \,dərmə'sentər, -,dəm-\ *n, cap* [NL, fr. *derma-* + Gk *kentōr* goader, fr. *kentein* to sting, prick, goad] : a large widely distributed genus of ornate eyed ticks (family Ixodidae) including a number that attack man and other mammals and several that are vectors of important diseases (as anaplasmosis of cattle, piroplasmosis of dogs, and Rocky Mountain spotted fever of man)

**der·mal** \'dərməl\ *adj* [*derm-* + *-al*] **1** : of or relating to skin, esp. to the dermis : CUTANEOUS **2** : ORIGINAL

**dermal ossicle** *n* : a small bone or concretion lying within the skin (as in various reptiles or the extinct ground sloths)

**dermal pore** *n* : one of the minute openings in the surface of a sponge that give access to the incurrent canals : OSTIUM

**der·ma·nys·sid** \,dərmə'nisəd\ *adj* [NL *Dermanyssidae*] : of or relating to the Dermanyssidae

**der·ma·nys·si·dae** \,dərmə'nisə,dē\ *n pl, cap* [NL, fr. *Dermanyssus*, type genus + *-idae*] : a family of parasitic mites having the chelicerae adapted for piercing and including several economically important forms (as the chicken mite and the tropical rat mite)

**der·ma·nys·sus** \-'nisəs\ *n, cap* [NL, fr. *derm-* + *nyssein* (fr. Gk *nussein* to prick)] : the type genus of Dermanyssidae comprising a number of blood-sucking mites that are parasitic on birds — see CHICKEN MITE

**der·map·tera** \(,)dər'maptərə\ *n pl, cap* [NL, fr. *derm-* + *-ptera*] : an order of insects consisting of the earwigs and usu. a few related forms parasitic on bats or rats — **der·map·ter·an** \(')-tərən\ *adj or n* — **der·map·ter·ous** \-tərəs\ *adj*

**dermasurgery** \'-,sərj(ə)rē\ *n* [*derm-* + *surgery*] : a branch of embalming that deals with the restoration of mutilated or destroyed features or members

**dermat-** *or* **dermato-** *comb form* [Gk. fr. *dermat-, derma*] : SKIN : HIDE (*dermatodynia*) (*dermatology*)

**-der·ma·ta** \'dərmətə, -,dəm-,sōd-, -əd\ *n pl comb form* [NL, fr. Gk *dermat-, derma*] : ones having a (specified) type of skin — in names of taxonomic categories of animals larger than a genus (*Scleractermata*)

**der·ma·tit·ic** \,dərmə'tidik, ,dəm-,dəim-, -'tid-\ *adj* [NL *dermatitis* + E *-ic*] : relating to dermatitis

**der·ma·ti·tis** \,dərmə'tīdəs, -'tid-\ *n, pl* **dermatitides** \-'tidə,dēz\ *or* **dermatitis·es** \-'tidəsəz\ [NL, fr. *derm-* + *-itis*] : inflammation of the skin typically marked by reddening, swelling, oozing, crusting, or scaling

**der·ma·to·bia** \-'tōbēə\ *n, cap* [NL, fr. *dermat-* + *-bia*] : a genus of botflies whose larvae live under the skin of domestic mammals and sometimes of man in tropical America

**der·mat·o·cranium** \(,)dər,madō'krānēəm, ,dərmad-ō-\ *n* [NL, fr. *dermat-* + *cranium*] : the part of the skull that develops in the form of membrane bone — compare CHONDROCRANIUM

**der·mat·o·gen** \(,)dər'madəjən, -,jen, 'dərmad-ə-\ *n* -s [ISV *dermat-* + *-gen*] **1** : the outer primary meristem of a plant or plant part that according to the histogen theory gives rise to epidermis **2** : the outer apical meristem of a root tip — called also PROTODERM

**der·mat·o·glyph·ic** \(,)dərmad·ə'glifik, ,dərmad-ō-\ *adj* [back-formation fr. *dermatoglyphics*] : of or relating to dermatoglyphics

**der·mat·o·glyph·ics** \-iks\ *n pl but sing or pl in constr* [*dermat-* + Gk *glyphein* to carve + *-ics* — more at CLEAVE] **1** : skin patterns: *specif* : patterns of the specialized skin of the inferior surfaces of the hands and feet **2** : the science of the study of skin patterns

**der·mat·o·graph** \(,)dər'madə,graf, 'dərmad-ə-\ *n* [*dermat-* + *-graph*] : an instrument for producing markings on the skin: as **a** : a crayon used by surgeons to outline internal organs on the body surface (sketch the outline of the liver with a ~ on the abdominal skin) **b** : a crayon used to test for allergies

**der·mat·o·graph·ia** \(,)dər,madə'grafēə, ,dərmad-ə-\ *or* **der·ma·tog·ra·phism** \,dərmə'tägrə,fizəm\ *n* -s [*dermatographia*, NL, fr. *dermat-* + *-graphia* -graphy; *dermatographism* fr. *dermat-* + *-graph* + *-ism*] : DERMATOGRAPHIA

**der·ma·tog·ra·phy** \,dərmə'tägrəfē\ *n* -ES [ISV *dermat-* + *-graphy*] : anatomical description of the skin

**der·mat·o·histology** \(,)dər,madō-, ,dərmad-ō- +\ *n* [*dermat-* + *histology*] : histology of the skin

**der·ma·toid** \'dərmə,tȯid\ *adj* [ISV *derma-* + *-oid*] : resembling skin

**der·mat·o·log·ic** \(,)dər,madəl'äjik, ,dərmad-ə-\ *or* **der·mat·o·log·i·cal** \-jikəl\ *adj* : of or relating to dermatology

science that is concerned with the skin, its structure, functions, and diseases

**der·ma·tome** \'dərmə,tōm\ *n* -s [ISV *derm-* + *-tome*] **1** : any instrument for cutting skin for use in grafting **2** a : the lateral wall of a somite from which the dermis is produced b : a segmental skin area delimited by nerve supply

**der·mat·o·mere** \(,)dər'madə,mi(ə)r, 'dərmad-ə-\ *n* -s [ISV *dermat-* + *-mere*] : DERMATOME 2

**der·ma·to·mi·tis** \,dərmətō'mītəs\ *also* **der·ma·to·mal** \-'tōməl\ *or* **der·ma·to·mat·ic** \(,)dər,mad·ə'matik\ *adj* : of or relating to a dermatome

**der·mat·o·my·cosis** \(,)dər,madə,mī'kōsəs, ,dərmad-ə-\ *n, pl* **dermatomycoses** \-,sēz\ [NL, fr. *dermat-* + *mycosis*] : DERMOMYCOSIS

**der·mat·o·my·co·sis** \-,mī'kōsəs\ *n, pl* **dermatomycoses** \-,sēz\ [NL, fr. *dermat-* + *mycosis*] : a disease of the skin caused by infection with a fungus

**der·mat·o·my·o·si·tis** \-,mīə'sīdəs\ *n* [NL, fr. *dermat-* + *myositis*] : a chronic inflammation of the skin, subcutaneous tissue, and skeletal muscles of unknown cause

**der·mat·o·path·ia** \-'pathēə\ *also* **der·ma·top·a·thy** \dər-'matəpəthē\ *n, pl* **dermatopathias** *also* **dermatopathies** [NL *dermatopathia*, fr. *dermato-* + *-pathia* -pathy] : disease of the skin — **der·ma·to·path·ic** \(,)dər,madə'pathik, ,dərmad-ə-\ *adj*

**der·mat·o·phyte** \(,)dər'madə,fīt, 'dərmad-ə-\ *n* -s [ISV *dermat-* + *-phyte*] : a fungus parasitic upon the skin or skin derivatives (as hair or nails) of man or lower animals — compare MYCOSIS FUNGOIDES — **der·mat·o·phyt·ic** \(,)dər,madə-'fitik, ,dərmad-ə-\ *adj* — **der·mat·o·phy·to·sis** \-,fī'tōsəs\ *n*

**der·mat·o·phy·tid** \,dər'madəfī,tid, ,dərmad-ə-\ *n* -s : a skin eruption associated with a fungus infection; *esp* : one considered to be due to allergic reaction

**der·ma·top·sy** \'dərmə,täpsē\ *n* -ES [ISV *dermo-* + *-opsy*] : sensitiveness of the skin to light (as in some worms) — **der·ma·top·tic** \-'täptik\ *adj*

**der·mat·o·sclerosis** *n, pl* **dermatosclerooses** \(,)dər,madō-,dərmad-ə-\ [NL, fr. *dermato-* + *sclerosis*] : SCLERODERMA

**der·ma·to·sis** \,dərmə'tōsəs\ *n, pl* **dermato·ses** \-,sēz\ [NL, fr. *dermat-* + *-osis*] : a disease of the skin

**der·mat·o·some** \(,)dər'madə,sōm, 'dərmad-ə-\ *n* -s [ISV *dermat-* + *-some*] : any of the minute particulate elements joined by cytoplasm that in one theory of cell-wall structure are held to make up the plant cell wall; *loosely* : a structural unit of cellulose in a plant cell wall

**der·mat·o·tome** \-,tōm\ *n* -s [*dermat-* + *-tome*] : DERMATOME 1

**dermatotropic** *var of* DERMOTROPIC

**-der·ma·tous** \'dərmətəs, -,dəm-, -mətəs\ *adj comb form* [NL *-dermatus* + E *-ous*] : having a (specified) type of skin (*scleroderm·atous*)

**der·mes·tes** \dər'mestēz\ *n, cap* [NL, fr. Gk *dermestēs* worm that eats skin or leather, fr. *derein* + *-stēs* (fr. *esthiein* to eat); akin to Gk *ethmenai* to eat — more at EAT] : the type genus of Dermestidae — see LARDER BEETLE, MYSTERIOUS BEETLE

**der·mes·tid** \dər'mestəd\ *adj* [NL *Dermestidae*, fr. *Dermestes*, type genus + *-idae*] : of or relating to the Dermestidae

**dermestid** \"\ *n* -s : a beetle of the family Dermestidae

**der·mes·ti·doe** \-ə,dō\ *n pl, cap* [NL, fr. *Dermestes*, type genus + *-idae*] : a family of small beetles that have clubbed antennae and are very destructive both as larvae and adults to organic material of animal origin (as dried meats, fur, wool, or insect collections)

**-der·mia** \'dərmēə, -,dəm-, -mēə\ *n comb form* [NL, fr. Gk *derma* skin + NL *-ia* — more at DERM-] : skin or skin ailment of a (specified) type (*pachydermia*)

**der·mic** \'dərmik\ *adj* [*derm-* + *-ic*] : DERMAL

**der·mi·tis** \'dərmətəs, -,dəm-, -,mītəs\ *n* -ES [*dermat-*] **1** : the sensitive vascular inner mesodermic layer of the skin made up chiefly of white fibrous connective tissue with some smooth muscle and elastic tissue and numerous nerves and sensory receptors — called also *corium, cutis* **2** : the uppermost layer of the thallus of many lichens that consists of one or more layers of irregular flattened hyphal cells with somewhat gelatinous walls

tended to ridicule an unfaithful spouse or a shrewish wife often with effigies and a mock serenade
**skim·mi·ty** \'skimə-tē, -mətē, -i\ *or* **skimmity ride** *n* -ES [*skimmity* alter. of *skimmington*] : SKIMMINGTON 2
**¹skimp** \'skimp\ *adj* [perh. alter. of *¹scrimp*] : barely sufficient : SCANTY, MEAGER ⟨a thin woman whose ~ dress hung flat —Elizabeth M. Roberts⟩
**²skimp** \"\ *vb* -ED/-ING/-S *vt* : to give insufficient or barely sufficient attention or effort to or funds for : SCAMP ⟨their homes are all facade — *~ed* under the superficial show —F.A. Swinnerton⟩ ~ *vi* : to save by or as if by skimping : SCRIMP ⟨we build schools without libraries, ~ on new-book budgets —Bice Clemow⟩ ⟨the two-dollar entry fee must have required a little *~ing* —Dixon Wecter⟩
**skimp·i·ly** \-pəlē, -li\ *adv* : in a skimpy manner
**skimp·i·ness** \-pēnəs, -pin-\ *n* -ES : the quality or state of being skimpy
**skimp·ing·ly** *adv* : in a skimping manner
**skimpy** \'skimpē, -pi\ *adj* -ER/-EST : deficient in supply or execution esp. through skimping ⟨a ~ and inadequate training —Elspeth Mosscrop⟩ SYN see MEAGER
**skims** *pres 3d sing of* SKIM, *pl of* SKIM
**¹skin** \'skin\ *n* -S *often attrib* [ME, fr. ON *skinn;* akin to OE *scinn* skin, MHG *schint* peel of a fruit, ON *skēn* crust, W *ysgythru* to cut, scratch, and prob. to L *secare* to cut — more at SAW] **1 a** : the integument of an animal separated from the body with or without hair whether green, dry, tanned, or dressed; *specif* : that of a small animal (as a calf, sheep, or goat) as distinguished from the hide of a large animal **b** : the hide or pelt of a game animal and esp. of one to be hunted **c** (1) : the pelt of an animal prepared for use as a trimming or in a garment ⟨her neckpiece of four *~s*⟩ ⟨it takes forty *~s* to make a coat⟩ (2) : a sheet of parchment or vellum made from the whole or part of a hide (3) : BOTTLE 1b (4) : SEALSKIN 3; *also* : a plush covering for a ski used like a sealskin — usu. used in pl. **2 a** : the external limiting layer of an animal body esp. when forming a tough but flexible cover relatively impermeable from without while intact: as (1) : the 2-layered covering of the vertebrate body sometimes modified by the presence of bony plates (as in an armadillo) or scales (as in most fishes and reptiles) and consisting of an outer ectodermal epidermis that is more or less cornified and penetrated by the openings of various glands (as sweat and sebaceous glands in man) and an inner mesodermal dermis that is composed largely of connective tissue and is richly supplied with blood vessels and nerves (2) : the hypodermis and the overlying cuticle that it secretes in many invertebrates — compare EXOSKELETON, MUCOUS MEMBRANE **b** : an outer covering of a fruit or seed (as a rind, husk, or peel) ⟨a black eye caused by a swiftly hurled orange ~ —*Amer. Guide Series: N.C.*⟩ **c** : the epidermis of a plant **d** (1) : a membranous film or scum (as on boiling milk or on the surface of paints or varnishes) : PELLICLE ⟨how cold the gravy was getting — a ~ was forming on it —Agatha Christie⟩ (2) : a thin frozen coating ⟨a ~ of ice⟩ **e** (1) : an outermost layer or surface of an object ⟨the ~ of a casting⟩ ⟨the ~ of a diamond⟩ ⟨the ~ of an electric conductor⟩ (2) : a layer and esp. the outermost layer of nacreous matter composing a pearl (3) : the surface of a bituminous pavement **f** : the part of a furled sail that is on the outside and covers the whole **g** : a casing for sausage **h** : the rind of ham or bacon **3** : the life or physical well-being of a person ⟨when the troopship went down he took care that if anybody's ~ was saved it should be his —Peter Forster⟩ **4** : a sheathing or casing forming the outside surface of a structure ⟨steel for auto *~s* —A.G.Tombs⟩: as **a** : a covering of planking or metal plates outside the framing that forms the sides and bottom of a ship : SHELL **b** : an exterior wall of a building: (1) : either of two panels that enclose a hollow space containing the framework ⟨external walls are of 11-inch cavity brickwork, with inner *~s* of cellular flettons —*Architectural Rev.*⟩ (2) : thin weather-resistant stainless steel, aluminum, or other metal used alone or in combination with glass and other material to form a curtain wall **c** : an outer sheet covering of an airplane, missile, or satellite that is in an airplane usu. made of metal and designed to carry a portion of the stress **5** : PURSE, POCKETBOOK **6** : a contemptible person: as **a** : MISER, SKINFLINT **b** : one given to cheating : SWINDLER, SHARPER **7** : MADE= BEAVER **8** *slang* : DAUM **9** : SKINBALL **10** [short for *frogskin*] *slang* : DOLLAR **11** *slang* : HORSE **12** [*²skin*] *slang* : an unfavorable report or a reprimand — **in a whole skin** *or* **with a whole skin** : without bodily harm : safe and sound — **in one's skin** : wearing no clothes : NAKED ⟨in every section a man stood *in his skin* while a doctor examined his teeth or palpated his chest —Robert Lynd⟩ — **out of one's skin** : in or into unrestrained expression of joy, enthusiasm, vigor, surprise, or other emotion : EXCITEDLY ⟨people . . . always jump *out of their skins* when they hear our own artillery — R.M.Ingersoll⟩ — **the skin of one's teeth** : a very narrow margin ⟨escaped by *the skin of my teeth* —Job 19:20 (RSV)⟩ — **under one's skin** : beneath one's surface powers of resistance to emotional or intellectual excitation : so deeply penetrative as to irritate, stimulate, provoke thought, or [illegible] *under his skin* a little . . . he